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October 3, 2005

OVERNIGHT COURIER 10/3/05

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam

This petition is submitted in quadruplicate under Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act, and in accordance with 21 CFR 10.30 on behalf of a client requesting the Commissioner of the Food and Drug Administration to declare that the drug products Efavirenz Tablets for Oral Suspension 50 mg, 100 mg and 200 mg, are suitable for submission in an abbreviated new drug application (ANDA).

A. Action Requested

The petitioner requests that Commissioner of the Food and Drug Administration make a determination that Efavirenz Tablets for Oral Suspension 50 mg, 100 mg and 200 mg are suitable for submission in an ANDA. The reference-listed drug product upon which this petition is based is Sustiva® (efavirenz) Capsules, 200 mg, manufactured by Bristol-Myers Squibb Company, which appears in the Electronic Orange Book (see **Attachment 1**). Therefore, the petitioner seeks a change in the dosage form (from capsules to tablets for oral suspension) from that of the listed drug product.

B. Statement of Grounds

The Federal Food, Drug and Cosmetic Act provides for the submission of an ANDA for a new drug that differs in dosage form from a listed drug provided the FDA has approved a petition that proposed the filing of such an application. Sustiva® (efavirenz) Capsules, the reference-listed drug upon which this petition is based, are available in capsule dosage form containing 200 mg, and are also approved and available in additional strengths containing 50 mg and 100 mg of efavirenz. The proposed drug products represent the same uses, strengths and route of administration; differing only in dosage form from the reference-listed drug.

In support of the change in dosage form requested in this petition, the petitioner would like to point out that the Agency has previously approved ANDA suitability petitions allowing for a similar change in dosage form (from capsule or tablet to tablet for oral suspension). In addition, the proposed drug product will be shown to be bioequivalent to the RLD.

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There are no proposed changes in labeling with exception of the obvious requirements based on a change in dosage form sought in this petition. However, it is recognized that it may be necessary for the labeling of the proposed product to differ due to exclusivity or patent protection related to the reference-listed drug. Draft labeling for the proposed product is included in **Attachment 2**. A copy of the referenced-listed drug product's labeling is included in **Attachment 3**. The petitioner is seeking this change in dosage form in an effort to make an alternate dosage form (tablet for oral suspension) available for those individuals that either have difficulty in swallowing a capsule, or who prefer a liquid dosage form.

Pediatric Use Information

In December of 2003, Congress passed the Pediatric Research Equity Act (PREA) that amended the Federal Food, Drug and Cosmetic Act (The Act) to provide the Agency authority to require drug firms to study certain drugs in pediatric patients, if the Agency felt that such a study would provide beneficial health data for that patient population.

Section 505B(a)(4)(A)(iii) of The Act (as amended by PREA) provides a provision for a waiver from providing assessments of pediatric use of a drug if:

(iii) the drug or biological product;

(I) does not present a meaningful therapeutic benefit over existing therapies for pediatric patients; and

(II) is not likely to be used in a substantial number of pediatric patients.

The petitioner hereby requests that a waiver from the conduct of pediatric studies of Efavirenz Tablets for Oral Suspension for all age groups be granted for this petition.

With respect to the Pediatric Research Equity Act, Efavirenz was on the historical list of Approved Drug Products for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population, and a written request from FDA was issued for pediatric studies. Those studies are ongoing; however, the package insert does contain information pertaining to pediatric studies and pediatric use. Additionally, the Agency's Summary Conclusions of Study ACTG 382 (pediatrics) states the following:

> **Although the study size is small and follow-up of short duration, the results provide pharmacokinetic results adequate to support dosing with efavirenz capsules in children ages 3 to 16 years. The pharmacokinetics of efavirenz in children aged 3-16 years is similar to those observed in HIV-infected adults.**

Since the product is being studied in the pediatric population and is also labeled for pediatric use, there would be no reason to repeat those studies or initiate additional studies to demonstrate what is already known or what will be known about the drug product.

Any ultimate approval of a product based on this petition would therefore not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in the age group not covered in existing labeling.

Therefore, since the innovator drug product has been appropriately studied in accordance with the concepts embodied in the PREA, the petitioner respectfully requests a waiver for the need to conduct pediatric studies.

C. Environmental Impact

The environmental assessment report on the action requested in this petition is not required under 21 CFR §25.31.

D. Economic Impact

Pursuant to 21 CFR 10.30 (b), economic impact information is to be submitted only when requested by the Commissioner. Information will be submitted, if requested.

E. Certification

The undersigned certifies that to the best of its knowledge, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully Submitted,

Robert Pollock pk

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RWP/pk

Attachments:

Attachment 1: Electronic Orange Book
Attachment 2: Draft labeling for the proposed product
Attachment 3: Referenced-listed drug product's labeling

cc: Arianne Camphire (Office of Generic Drugs)

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